

REMARKS**Status of the Claims**

Claims 18, 19, 27, 34, and 35 are pending in this application.

Claims 20-26, 28, 30, and 31-33 are cancelled herein without prejudice or disclaimer of Applicants' right to represent the cancelled subject matter in this or a divisional application.

Claims 18, 19, and 27 are amended herein and are fully supported by the specification as filed. No new matter is introduced.

New claims 34 and 35 are added herein and are fully supported by the specification as filed. No new matter is introduced.

Claim Rejections**35 U.S.C. §112, second paragraph**

Claim 28 is rejected under 35 U.S.C. §112, second paragraph as being indefinite. Applicants have cancelled claim 28 herein, so the rejection is now moot. Applicants therefore respectfully request that the rejection under 35 U.S.C. §112, second paragraph be withdrawn.

35 U.S.C. §112, First Paragraph: Written Description

Claims 20-28 and 30-33 are rejected under 35 U.S.C. §112, first paragraph. The Examiner states that the claims do not define the structure of any polymorphisms located between D9S59 and D9S127 in terms of their nucleotide identity or location, and that they do not define the gene associated with familial dysautonomia in terms of a particular chemical structure. The Examiner states that there are no teachings in the specification or the prior art as to the length of the gene and the positions of the exons or introns. The Examiner also indicates that while Applicants were in possession of nine polymorphisms described in the specification, there is insufficient information provided in the specification to indicate that Applicants were in possession of the broadly claimed genus of any polymorphism in the region between D9S59 and D9S127 at the time of filing. Applicants respectfully traverse this rejection, and assert that as

described in the response filed on October 10, 2007, Applicants have identified numerous markers within this range that are closely and significantly linked to the FD gene (i.e., that have a LOD score of greater than 3). In addition, an understanding of the exact nature of the gene responsible for a disease is not necessary in order to perform linkage analysis to identify polymorphisms which can serve as markers for the defective allele, and to identify individuals which are carriers for a hereditary disorder by detecting those specific polymorphisms. However, in order to advance prosecution, Applicants have cancelled claims 20-26, 28, 30, and 31-33, and have added new claims 34 and 35, which recite “determining whether a polymorphism selected from the group consisting of D9S59, D9S53, D9S58, D9S105, D9S309, D9S310, D9S172, D9S174 and D9S127 is present.” Applicants therefore respectfully request that the rejection under 35 U.S.C. §112, first paragraph be withdrawn.

35 U.S.C. §112, First Paragraph: Enablement

Claims 20-28 and 30-33 are rejected under 35 U.S.C. §112, first paragraph because the Examiner states that while the specification is enabling for detecting the disclosed polymorphisms linked to a gene associated with FD, the claims are not enabled for detecting the presence of any polymorphism located between D9S59 and D9S127. Applicants respectfully traverse the rejection.

The Examiner states that the instant claims are not enabled because the specification does not teach any wildtype or defective genes associated with FD, and because the specification does not teach a representative number of polymorphisms associated with FD within the claimed region. As described above, and more fully in Applicants’ response filed on October 10, 2007, the exact location of the gene and the structural features of the gene are not necessary for performing Applicants’ invention. The invention is based on linkage analysis, the nature of which specifically does not require the knowledge of the specific attributes or even the precise location of the gene in question, because the polymorphisms identified segregate with the FD phenotype and have significant LOD scores such that they can be used in genetic screening tests for FD. In addition, Applicants have significantly narrowed the range in which to search for polymorphisms associated with FD in the instant application, and have provided more than

sufficient disclosure to enable one of skill in the art to determine additional makers associated with the FD gene within the claimed genus. However, in order to advance prosecution, Applicants have cancelled claims 20-26, 28, 30, and 31-33, and have added new claims 34 and 35, which recite “determining whether a polymorphism selected from the group consisting of D9S59, D9S53, D9S58, D9S105, D9S309, D9S310, D9S172, D9S174 and D9S127 is present.” Applicants therefore respectfully request that the rejection under 35 U.S.C. §112, first paragraph be withdrawn.

Nonstatutory Type Double Patenting

Claims 20-28 and 30-33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 5,998,133 and claims 1-16 of U.S. Patent No. 5,387,506. Without agreeing with the Examiner’s characterization of the claims, Applicants will file an appropriate terminal disclaimer upon indication of allowable subject matter.

35 U.S.C. §102(a)

Claims 20-28 and 30-33 are rejected under 35 U.S.C. §102(a) as being anticipated by Kwiatkowski. Applicants respectfully traverse the rejection.

The Examiner states that Kwiatkowski describes a method for detecting the presence of a D9S59 polymorphism, and that an inherent property of this polymorphism is that it is linked to a gene associated with FD. Kwiatkowski describes the nucleic acid sequence for detecting D9S59, but does not teach or suggest that this polymorphism is linked to the FD gene, or that this marker can be used to identify individuals carrying the gene associated with FD. The instant claims are not anticipated by Kwiatkowski. However, to advance prosecution, Applicants have cancelled claims 20-26, 28, 30, and 31-33, and have added new claims 34 and 35, which recite: “predicting for said subject the transmission or development of familial dysautonomia based on the presence or absence of said polymorphism.” It is clear that Kwiatkowski does not teach or suggest at least this step.

In view of at least the foregoing, Applicants respectfully request withdrawal of this ground of rejection.

CONCLUSION

Based on the foregoing remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of claims and allowance of this application.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. 50-3732, Order No. 13572.105040.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 50-3732, Order No. 13572.105040.

Respectfully submitted,

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